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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,030	04/13/2006	Masanori Yamaguchi	TOYA149001APC	2081

20995 7590 06/12/2008
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EXAMINER

LAU, JONATHAN S

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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06/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/576,030	Applicant(s) YAMAGUCHI ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-34 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9 pgs/ 14Apr2006, 26May2006, 19Mar2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is the national stage entry of PCT/JP04/15174, filed 14 Oct 2004; and claims benefit of foreign priority documents JAPAN 2003-353490, filed 14 Oct 2003; JAPAN 2003-353491, filed 14 Oct 2003; JAPAN 2004-018128, filed 27 Jan 2004; and JAPAN 2004-194088, filed 30 Jun 2004; currently no English language translation of any of said foreign priority documents are of record.

Claims 1-47 are pending in the current application. Claims 1-34 and 47, drawn to non-elected inventions, are withdrawn. Claims 35-46 are examined on the merits herein.

Election/Restrictions

Applicant's election with traverse of the invention of Group XVI, claims 35-46, in the reply filed on 18 Mar 2008 is acknowledged. The traversal is not found persuasive because no errors in the restriction requirement are indicated.

The requirement is still deemed proper and is therefore made FINAL.

Claim 1-34 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 18 Mar 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 36, 42, 43, 45 and 46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites "in an amount two times or more larger than that of scyllo-inositol dissolved" in line 4.

Claim 42 recites "ethanol is added in a volume 0.3 to 3 times larger" in line 2 and "methanol is added in a volume 0.3 to 5 times larger" in line 3.

Claim 43 recites "ethanol is added in a volume 0.6 to 1.5 times larger" in line 2 and "methanol is added in a volume 0.9 to 2 times larger" in line 3.

Claim 45 recites "ethanol is added in a volume 0.2 to 0.4 times larger, the methanol is added in a volume 0.2 to 0.8 times larger, or the 1-propanol is added in a volume 0.2 to 0.4 times larger" in lines 2-4.

Claim 46 recites "ethanol is added in a volume 0.35 to 0.45 times larger, the methanol is added in a volume 0.45 to 0.55 times larger, or the 1-propanol is added in a volume 0.35 to 0.45 times larger" in lines 2-4.

The term "amount" in claim 35, line 4 is indefinite because it fails to particularly point out the units of the amount, such that it may be an amount by weight, by volume, or by mol for example.

The phrase "times larger" renders the claim indefinite because it fails to particularly point out an amount. For example if there is 1 unit of scyllo-inositol dissolved, "two times ... larger than that of scyllo-inositol dissolved" disclosed in claim 35 may refer, to an amount that is 2 units, two times that of scyllo-inositol dissolved, or 2+1, or 3 units, two times **larger than** that of scyllo-inositol dissolved. Therefore if there is 1 unit of scyllo-inositol dissolved the phrase "two times ... larger than that of scyllo-inositol dissolved" is indefinite because it may refer to either 2 or 3 units.

Further, claim 45 recites, "ethanol is added in a volume ... 0.4 times larger ... than that of the acidic solution." By analogous reasoning, if the volume of the acidic solution is 1 unit, the volume of ethanol may be 0.4 units, or 0.4 times that of the acidic solution, which is **not** larger than the acidic solution, or it may be 0.4+1 units, 0.4 times larger than the 1 unit volume of the acidic solution.

Claim 36 recites the limitation "the amounts of the boric acid and metal salt to be added is not less than twice mol, and not more than three times of the scyllo-inositol dissolved in the liquid mixture " in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. As recited above there is indefiniteness introduced by the phrase "times larger". Based on an interpretation of usage in claims 45 and 46, for example "0.4 times larger", the phrase "two times or more larger than that of scyllo-inositol dissolved" is interpreted to mean, if there is 1 mol of scyllo-inositol dissolved, the amount of boric acid is 2 times **larger**, 2+1, or 3 mol boric acid or more. Claim 36 requires the amount of boric acid to be not more than 3 times the mol of the scyllo-inositol dissolved. The only overlap between the range of amounts of boric acid in claim

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35, "two times or more larger", and claim 36, "not more than three times", is exactly 3 times the amount of scyllo-inositol dissolved, based on the language used in claims 42, 43, 45 and 46.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006). As DE 3405663 is published in German, a machine translation of the document is provided; all citations of Merck herein

refer to the machine translation. Sigma-Aldrich (Technical Information Bulletin AL-142, Sigma-Aldrich, cited in PTO-892) is provided as evidence of the composition of Amberlite MB-3 resin.

Merck discloses a procedure for the production of scyllo inositol ("scyllo Inosit" from myo Inosose (page 1, paragraph 8). Merck discloses the procedure using the boric acid, sodium borohydride (page 2, paragraph 6). Merck discloses acidifying the scyllo-inositol-boron complex with 2N hydrochloric acid to separate the borate (page 2, paragraph 12), treating the complex of boron and scyllo-inositol with acid. Merck discloses separating the scyllo-inositol as crystals (page 2, paragraph 13), isolating and purifying the scyllo-inositol from the acid solution. The above steps meet limitations of instant claim 35. Merck discloses the conversion performed in a basic environment, in the presence of an added metal salt such as Na_2CO_3 ("Natriumcarbonat"), NaHCO_3 ("Natriumhydrogencarbonat"), K_2CO_3 ("potassium carbonate") and KHCO_3 ("potassium hydrogencarbonate") (page 2, paragraph 2), meeting limitations of instant claim 38. Merck discloses filtration with a cation exchanger column (page 2, paragraph 12), or a strong acidic ion exchange resin, meeting a limitation of instant claim 40. Merck discloses crystallization by adding methanol (page 2, paragraph 12), an aqueous organic solvent, meeting a limitation of instant claim 41-43.

Merck does not expressly disclose the amount of boric acid is not less than twice mol and not more than three times the scyllo-inositol dissolved in the mixture (instant claims 35 and 36). Merck does not specifically disclose adjusting the pH of the mixture to 8.0 to 11.0 or 9.0 to 10.0 (instant claims 35 and 37). Merck does not specifically

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disclose the method wherein the mixture contains myo-inositol and scyllo-inositol and is obtained by reducing scyllo-inosose (instant claim 39). Merck does not specifically disclose the method wherein method wherein the acidic solution is contacted with a strong acidic ion exchange resin and a strong basic ion exchange resin (instant claim 40). Merck does not specifically disclose the method wherein the amount of methanol is added in a volume 0.3 to 5 or 0.9 to 2 times larger than that of the acid solution (instant claims 42 and 43).

Weissbach teaches scyllitol, or scyllo-inositol, forms a diborate complex with two borate moieties (page 329, right column, figure 1). Weissbach teaches reduction of scyllo-myo-inosose with sodium borohydride generates a mixture of scyllitol and myo-inositol (page 329, right column, paragraph 2). Weissbach teaches the precipitation of the complex of scyllo-inositol and borate (page 329, right column, paragraph 2), the separation of the complex from the mixture. Weissbach teaches the diborate complex of scyllo-inositol is easier to separate from myo-inositol (page 329, left column, paragraph 3). Weissbach teaches the acidification of the complex of scyllo-inositol and borate and the contacting of the solution with the resin Amberlite MB-3 (page 330, left column, paragraph 1), a mixture of strongly acidic and strongly basic resins as evidenced by Sigma-Aldrich (Sigma-Aldrich, page 4, section 5. Amberlite Monobed Resin).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the process disclosed by Merck with the teaching of Weissbach. Both the inventions of Merck and Weissbach are drawn to the production of scyllo-

inositol by reduction of inosose with sodium borohydride. One of ordinary skill in the art would be motivated to combine process disclosed by Merck with the teaching of Weissbach because Weissbach teaches the diborate complex of scyllo-inositol is easier to separate from myo-inositol. Weissbach teaches scyllo-inositol forms a diborate complex with two borate moieties, which provides guidance to one of ordinary skill to select the amount of boric acid to use relative to the amount of scyllo-inositol present. Adjustments of pH, disclosed by Merck, and adjustments in the amount of a recrystallization solvent are generally known to one of ordinary skill in the art, and are known to be optimized by routine experimentation, see MPEP 2144.05 II.

Claim 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merck (DE 3405663, published 22 Aug 1985, provided by Applicant on IDS mailed 26 May 2006) in view of Weissbach (Journal of Organic Chemistry, 1958, 23, p329-330, provided by Applicant on IDS mailed 26 May 2006) as applied to claims 35-43 above, and further in view of Husson et al. (Carbohydrate Research, 1998, 307, p163-165, cited in PTO-892).

Merck in view of Weissbach renders unpatentable as above. Merck discloses crystallization of scyllo-inositol by adding methanol (page 2, paragraph 12).

Merck in view of Weissbach does not explicitly teach the step of precipitating only scyllo-inositol by adding an aqueous organic solvent to the acidic solution in an amount such that the myo-inositol is not precipitated. Merck in view of Weissbach does not

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explicitly teach the methanol is added in a volume 0.2 to 0.8 times or 0.45 to 0.55 times larger than that of the acidic solution.

Husson et al. teaches scyllo-inositol is separated from a mixture of inositols due to its very low solubility in alcohol (page 163, left column, middle of paragraph 1).

Husson et al. teaches scyllo-inositol has significantly different solubility than myo-inositol (page 163, right column, middle of paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the process rendered obvious by Merck in view of Weissbach with the teaching of Husson et al. Both the inventions of Merck in view of Weissbach and Husson et al. are drawn to the production and isolation of scyllo-inositol. It would have been use of a known technique to improve similar methods in the same way to combine Merck in view of Weissbach with the teaching of Husson et al. Adjustments in the amount of a recrystallization solvent are generally known to one of ordinary skill in the art, and are known to be optimized by routine experimentation, see MPEP 2144.05 II.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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